REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this amendment, claims 1-4, 7-9, 12, 13, 15-21, 39, and 40 will be pending in the present application.

The notice of allowable subject matter regarding claims 10 and 11 is appreciated. Claims 10 and 11 were deleted and new claims 39 and 40 are presented in this amendment. Claim 39 combines the subject matter recited in claims 1, 9, and 10. Claim 40 combines the subject matter recited in claims 1, 9, 10, and 11. Notice that claims 39 and 40 are allowed is earnestly solicited.

Claims 1-4 and 8 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,082,544 to Romick ("the '544 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

The medicine unit dose dispensing system disclosed in the '544 patent provides a system for exchanging medication blister strips held in a disposable dispensing frame. The dispensing frame includes a plurality of cartridge holes and arm holes. A prepackaged blister strip of pills is placed into the dispensing frame. Pills are dispensed by applying pressure on the blister strip to break a frangible membrane and release a pill. This reference also discloses that the device could have an information card attached to the device with a bar code. The information encoded on the bar code is readable by a scanner.

Although bar codes can store information, the device disclosed in the '544 patent does not anticipate the present invention. If anything, this reference exemplifies the deficiencies present in the art. The present application notes in the background that drug vials having a bar code are known in the art. However, this arrangement is undesirable. The bar code must be read by a scanner thereby requiring a direct line of sight between the bar code and scanner. Moreover, bar codes cannot be modified, and the amount of information they are capable of storing is very limited. In addition, the bar code is often adhered to each vial thus increasing manufacturing

costs and potentially necessitating regulatory approval in many countries. The present invention seeks to overcome these drawbacks.

In contrast with the device disclosed above, claim 1 of the present invention includes an electronic data carrier. A bar code is not an electronic device, and cannot be construed as an electronic data carrier. Secondly, claim 1 recites that the electronic data carrier includes a read/write memory. One substantial advantage provided by the present invention is that information can be easily stored, retrieved, modified, and transported on a removable electronic data carrier with a read/write memory. Data stored in a bar code cannot be updated. Therefore, a medicine unit dose dispensing device with a bar code cannot anticipate or render obvious the present invention.

For the reasons presented above, applicant respectfully submits that independent claim 1 is not anticipated or rendered obvious by the '544 patent. In addition, claims 2-4 and 8 are also not anticipated or rendered obvious due to their dependency from independent claim 1. Accordingly, applicant respectfully requests that the above rejection of claims 1-4, and 8 be withdrawn.

Claims 13, 15, 16, 18, and 20 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,593,390 to Castellano et al. ("the '390 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

The medication delivery device disclosed in the '390 patent is described as being a pen-type injector, jet injector, medication pump, inhaler, or spray. The device includes a microprocessor with memory housed in the device to record the date, time, and amount of each medication delivered. As noted in the abstract, the '390 patent states that this device provides a single, all-in-one device capable of performing a variety of functions and requires a minimum of space.

Although integrated devices housing multiple items together have their advantages in some applications, an integrated device would be incapable of providing the unique advantages of the present invention. The present invention also discloses internal electronics, and has a controller in the nebulizer. The '390 patent does not, however, suggest or

disclose a removable electronic data carrier. By having a removable electronic data carrier, information can be easily stored, modified, retrieved, and transported. For example, enclosing a removable electronic data carrier with a drug package results in few manufacturing complications. However, packaging a separate drug device with each drug package would be bulky and far more expensive. It would be inconvenient for users to directly retrieve information from the device disclosed in the '390 patent. The user would have to either transport the entire device or directly connect it to an external computer via the I/O port. The present invention provides a removable electronic data carrier that can be easily transported. This configuration also has the further advantage of allowing the user to reuse a single drug delivery device with multiple different drugs. The device can be reprogrammed by merely selecting the appropriate electronic data carrier. This reference exemplifies the drawbacks present in the state of the art and highlights the need for a cost effective and simple manner to store, modify, and retrieve treatment information.

In contrast with the device disclosed in the '390 patent, the present invention, as recited in claims 13 and 20 recites an electronic data carrier that is removable from the drug delivery apparatus. If anything, the '390 patent teaches away from the present invention. It merely teaches housing electronics inside a medical device and in no way discloses or suggests the removable electronic data carrier of the present invention.

For the reasons presented above, applicant respectfully submits that independent claims 13 and 20 are not anticipated or rendered obvious by the '390 reference. In addition, claims 15, 16, and 18 are also not anticipated or rendered obvious due to their dependency from independent claim 13. Accordingly, applicant respectfully requests that the above rejection of claims 13, 15, 16, 18, and 20 be withdrawn.

Claim 19 stands rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,505,195 to Wolf et al. ("the '195 patent"). Applicant respectfully traverses this rejection.

The dry dose powder inhalant device disclosed in the '195 patent is mounted on a dry powder dispenser having a mouthpiece to deliver dry powder medication to a patient. The

device includes a housing that is mounted on the dispenser for computing and recording when a proper amount of medication has been delivered to the patient. The microprocessor computes and records when a proper amount of dry powder is released.

Indeed the housing retaining the microprocessor and memory could be disassembled from the dry powder inhalant apparatus. However doing so presents several drawbacks. The electronics housing cap 110 is an integrated part the dry powder inhalant device that is screwed onto the metered dose inhalant dispenser. Performing this operation may prove to be difficult for some users and could result in contamination of the device. Moreover, the electronics housing end cap is still a rather bulky device and thus can not achieve the ease of transportability provided by the present invention.

In contrast, the present invention provides an electronic data carrier that is removable from the drug delivery apparatus. With a removable, electronic data carrier, information can be easily transported without a bulky device as would be required in the '390 patent. The dry powder inhalant apparatus shown in FIG. 1 of the '195 patent may be construed to have multiple components that can be disassembled. Even so, this structure correlates with the nebulizer controller than the removable electronic data carrier and not the electronic data carrier.

For the reasons presented above, applicant respectfully submits that independent claim 19, as amended, is not anticipated or rendered obvious by the '195 reference. Accordingly, applicant respectfully requests that the above rejection of claim 19 be withdrawn.

Claim 21 stands rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,571,790 to Weinstein ("the '790 patent"). Applicant respectfully traverses this rejection.

The method and device for organizing and coordinating the combined use of liquid medications for continuous nebulization is a device adapted to assist users in properly mixing two-part medications. The device includes two sets of liquid held in a unifying container which includes indicia to distinguish the liquids and instructions for their proper mixing. This reference also exemplifies the drawbacks present in the art. The administration of the drugs, proper mixing, and accurate dispensing are all done manually by the user. This manual drug

delivery system does not in any way disclose or suggest the automated method provided by the electronics disclosed and claimed in the present invention. Claim 21 recites supplying a removable electronic data carrier, and transmitting treatment information. Neither of these features are disclosed in the '790 patent.

For the reasons presented above, applicant respectfully submits that independent claim 20 is not anticipated or rendered obvious by the '790 reference. Accordingly, applicant respectfully requests that the above noted rejection of claim 21 be withdrawn.

Claims 1-4, 7, 8, and 12 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,505,195 to Wolf ("the '195 patent") in view of the examiner's notice. Applicant respectfully traverses this rejection for the reasons presented below.

The dry dose powder inhalant device disclosed in the '195 patent is mounted on a dry powder dispenser having a mouthpiece to deliver dry powder medication to a patient. The device includes a housing that is mounted on the dispenser for computing and recording when a proper amount of medication has been delivered to the patient. A microprocessor computes and records when a proper amount of dry powder is released. If the physician wishes to change the dose of medication or the prescribed drug altogether, it would be necessary to return the entire nebulizer for reprogramming or directly connect the device to an external computer.

As discussed above with respect to claim 19, the structure identified by the examiner as being an electronic data carrier in the '195 patent is not removable. Even if this same feature is deemed to be a drug vial (or container), the reference still does not disclose or suggest having an electronic data carrier that is removable from a vial (or container). Indeed the electronics housing end cap retaining the microprocessor and memory could be disassembled from the dry powder inhalant apparatus. However doing so presents several drawbacks. The electronics housing cap 110 is an integrated part of the dry powder inhalant device and is screwed onto the metered dose inhalant dispenser. Performing this operation may prove to be difficult for some users. It also exposes the inside of the device to the external environment, and could result in contamination or harm to the user. Moreover, the electronics housing end cap is

still a rather bulky device and thus cannot achieve the ease of transportability provided by the present invention.

For the reasons presented above, applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. In addition, claims 2-4, 7, 8, and 12 are also not rendered obvious due to their dependency from independent claim 1. Accordingly, applicant respectfully requests that the above rejection of claims 1-4, 7, 8, and 12 be withdrawn.

Claim 9 stands rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,082,544 to Romick ("the '544 patent") in view of U.S. Patent No. 5,593,390 to Castellano et al. ("the '390 patent"). Applicant respectfully traverses this rejection for the same reasons cited above with respect to the Romick rejections to claims 1-4, and 8 under 35 U.S.C. § 102(e). Applicant respectfully submits that claim 9 is not rendered obvious by the cited references due to its dependency from independent claim 1. Accordingly, applicant respectfully requests that the above rejection of claim 9 be withdrawn.

Claim 17 stands rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,593,390 to Castellano et al. ("the '390 patent") in view of U.S. Patent No. 5,505,195 to Wolf et al. ("the '195 patent "). For the reasons presented above with respect to the respect to the rejections to claims 13, 15, 16, 18, and 20 under 35 U.S.C. § 102(b), applicant respectfully submits that independent claim 13, as amended, is not anticipated or rendered obvious by the '390 reference. The addition of the '195 patent does not supplement the deficiencies noted above. Accordingly, applicant respectfully requests that the above rejection of claim 17 be withdrawn.

Claims 22-38 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,505,195 to Wolf et al. ("the '195 patent") in view of U.S. Patent No. 6,328,699 to Eigler et al. ("the '699 patent"). These claims have been cancelled. Applicant respectfully requests that this rejection be of claims 22-38 be withdrawn.

Aside from the amendments to the claims discussed above, other amendments to the claims have been made for the purposes of clarity. The recitation of "a vial" or "vials" was replaced with the terms "container" or "plurality of containers." These amendments were not

made to overcome any rejection made by the examiner. Instead, they are intended to clarify that any suitable container can be used in the present invention. Secondly, the term "data carrier" was amended to recite that it is an "electronic data carrier." This amendment was also not made in response to a rejection made by the examiner. Neither of these amendments was made to the new claims 39 and 40 since these claims are believed to be in a condition for allowance as noted by the examiner.

This response is being filed within the three-month statutory response period which expires on February 16, 2005. No additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is authorized to charge the any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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